

REMARKS

The Applicants have carefully reviewed the Final Office Action of May 29, 2007, in which claims 1, 3-15, 17-54 and 59-62 are pending and have been rejected and claims 23-54, 61 and 62 have been withdrawn from consideration. Favorable reconsideration is requested.

Propriety of Making Office Action Final

Applicants respectfully request that the finality of the Office Action of May 29, 2007 be withdrawn. A second or subsequent action can only be properly made final when no new grounds of rejection are introduced, except those new grounds that are based on applicant's amendment or on an IDS submitted under 37 C.F.R. 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP 706.07(a).¹ The Office Action of May 29, 2007 introduces new grounds of rejection. For example, on page 8, claims 1, 3-7, 12-15, 17, 21-22 and 59-60 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson et al., U.S. Patent No. 6,673,025 (hereinafter "Richardson") in view of Hodgson et al., U.S. Patent No. 5,345,945 (hereinafter "Hodgson"). This ground of rejection was not made in any previous office action. Moreover, the last response made no claim amendments²; neither was an IDS submitted under 37 C.F.R. 1.97(c). Therefore the May 29, 2007 Office Action could not have properly been made final and applicants respectfully request that the finality of this office action be withdrawn.

Claim Amendments

Claims 63-66 have been added. No new matter has been added. Support for the amendment may be found in, for example, Figure 3 and in the paragraph beginning page 7. As

¹ "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)."

² In paragraph 1 of the office action, it is incorrectly stated that claims 1 and 14 had been amended in the January 5, 2007 response. Applicants speculate that this language was inadvertently copied from the November 14, 2006 Final Office Action, where it first appears.

discussed above, the Office Action of May 29, 2007 was not properly made final; applicants can therefore amend under 37 C.F.R. § 1.112. Applicants respectfully submit that these newly presented claims are patentable because the cited prior art does not disclose the invention of these claims nor suggest the desirability of the claimed features and because these claims depend from independent claims 1 and 14, which applicants submit are patentable, as discussed below. Favorable consideration is respectfully requested.

Claim Rejections

Claims 1, 3-7, 12-15, 17, 21-22 and 59-60 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson. Applicants respectfully traverse the rejection.

It is respectfully noted that this rejection in view of Richardson is substantially identical to the rejection made in the last final Office Action dated November 14, 2006, with the exception of the proposed motivation for modifying the Richardson reference on pages 5 and 7 of the current Office Action. It is also noted that the November 14, 2006 Final Office action was appealed, and in pre-appeal conference, a decision was made to re-open prosecution.

In making this rejection once again, the Examiner first goes through each claim, listing the elements of Richards that the Examiner believes corresponds to the elements of the claims. On page 5 of the Office Action, the Examiner first makes a general statement about the extent of Richardson's disclosure with respect to Applicants' device and then makes a general statement of motivation. Finally, beginning on the bottom of page 5, the Examiner makes a § 103 rejection over several embodiments of Richardson. In this response, applicants will first point out errors made in the general statements on page 5 and then the errors made in the obviousness rejection, specifically disputing the correspondence of elements of Richardson and the claims to the extent necessary to show the deficiencies in the obviousness rejection. This, of course, should not be taken to mean that applicants necessarily agree with all statements of the Examiner that are not specifically discussed herein.

On page 5 of the Office Action, the Examiner argues that "Richardson et al. disclose a guidewire comprising a plurality of polymer layers substantially arranged in the same manner as Applicant's device with the exception that Applicant has explicitly identified an inner polymer layer as a 'tubular member.' (see Applicant's drawings, figs. 3-4 and Richardson et al., figure 20;

column 6/lines 1-24).” If this statement is intended to mean that this difference in terminology is the only difference between the guidewire of claim 1, for instance, and that of Figure 20 of Richardson, the statement is incorrect. For example, claim 1 recites “wherein the distal end of the coil member extends distally beyond the distal end of the tubular member.” In Richard, the Examiner equates element 156 with the tubular member and element 151 with the coil member. As can be seen by reference to Figure 20, helical coil 151 does not extend distally of first polymer layer 156. This point was first raised in the September 1, 2006 reply to the previous Office Action and was not disputed by the subsequent Office Action of November 14, 2006, which instead modified this rejection. This modified rejection was maintained through an Advisory Action of January 16, 2007. However, when applicants decided to appeal the rejection of the pending claims, this rejection was evidently thought inadequate in the Pre-Appeal Brief conference, which reopened prosecution. Therefore, this statement of the Examiner’s is incorrect at least for the reasons given and not disputed in a previous communication with the Office.

Next on page 5, the Examiner argued motivation for making a modification of Richardson by arguing that “such a modification would serve the same purpose of enhancing the performance of the guidewire and providing the guidewire with a substantially constant outer transverse dimension which translates smoothly in an axial direction within catheter lumens, intracorporeal channels, or the like.” (See Richardson et al., column 19/lines 15-25; column 20/lines 15-20.) This supposed motivation is problematic. First, the guidewire of figure 20 has a substantially constant outer transverse dimension and cannot in this manner be enhanced. Second, the portion of the specification that teach that making the first and second polymer layers 156 and 157 of different materials “to enhance the performance of the guidewire” describe the potential advantages of guidewire of Figure 20 and thus cannot be a motivation to modify the guidewire of Figure 20. Applicants therefore respectfully submit that motivation is lacking to make the suggested modification.

The Examiner then proceeds to make an obviousness rejection based on the combination of Figure 20 of Richardson in view of Figures 23 and 32 of Richardson, arguing that “it would have been obvious...to provide a guidewire similar to that of Richardson et al.’s first embodiment with a coil that extends distally beyond the distal end of the tubular member similar

to that of Richardson et al.'s second embodiment since such a modification would serve the same purpose of fluoroscopically tracking and/or imaging the distal end of the guidewire (see Richardson et al., column 5/lines 39-60)." Office Action at pages 6-7.

Such an obviousness rejection is difficult to respond to because it relies on a false premise. Contrary to the Examiner's assertion, the coil in the second embodiment of Richardson does not extend distally beyond the distal end of the tubular member. Applicants note that the Examiner has, on page 6 of the Office Action, drawn a dashed line at the proximal end of the solder mass and called the portion of the polymer layer 191 proximal to that line the tubular member. However in Richardson, polymer layer 191 does not end at the Examiner's line; it extends distally of the coil to the distal end of the guidewire. This can be seen clearly by reference to the cross-hatching in Figure 23. Thus the supposed basis for the motivation does not in fact exist.

Applicants raised a similar point in the January 5, 2007 response which, after apparent disagreement in the Advisory Action of January 16, 2007, was further discussed in the pre-appeal conference brief. The decision in the pre-appeal conference to reopen prosecution does not supply the reason why prosecution was reopened. However, if the Examiner continues to interpret Figure 23 of Richardson as has been done in previous office actions, it is respectfully requested that a detailed response to applicants' arguments in the second paragraph on page 3 of the pre-appeal brief of February 14, 2007 as to why such an interpretation is at odds with Richardson should be included in the interests of furthering prosecution.

Applicants further dispute that there is any motivation to look beyond the teachings of Richardson with regard to the guidewire of Figure 20 for fluoroscopic tracking and/or imaging. The guidewire of Figure 20 is already radiopaque. As Richardson teaches in column 20, lines 53-58, "excepting noted differences, the features...of guidewire 140 can be generally the same as the features...of similar elements of guidewire 110 discussed above." Guidewire 140 is the guidewire of Figure 20 and guidewire 110 is the guidewire discussed immediately before guidewire 140. Richardson teaches two different methods of making guidewire 110 radiopaque. First, "other materials suitable for the proximal helical coil...and suitable for the helical coils of other embodiments of the invention discussed herein, can include radiopaque metals and alloys." Column 18, lines 10-14. Second, in reference to a polymer layer to dispose about the core

member and coils, "any of the aforementioned polymers may be loaded with additives to control the physical properties such as flexural modulus, hardness and radiopacity." Column 19, lines 45-47. The disclosure with respect to Figure 20, therefore, already discloses a fluoscopically trackable guidewire in which the whole of the distal end, if desired, is radiopaque. Richardson therefore fails to teach anything with respect to the embodiment of Figure 23 which would further enhance the embodiment of Figure 20 in this regard.

Further, applicants can see no method taught by Richardson of extending the coil of Figure 20 distally that would result in the claimed invention. For example, in Figure 20, Richardson teaches disposing the coil about layer 156. Thus, if one were to extend the coil according to Figure 20, one would also extend layer 156 to support the coil. The distal end of the coil would therefore not extend distally of the distal end of the tubular member, as required in claim 1 for example. Likewise, figure 23 teaches attaching solder body 185 to the distal end of core 176. Once that is done, the tubular member would not extend distally of the distal end of the core member, as is also required by claim 1 for example.

Therefore, at least for the reasons that the cited prior art does not teach or suggest the claimed invention and that there is no motivation or suggestion to make the proposed modification, applicants submit that a prima facie case of obviousness has not been made and that claim 1 is in condition for allowance.

As claim 14 recites "wherein the distal end of the coil member extends distally beyond a distal end of the tubular member" and claim 59 recites "a ribbon or wire connected to and extending distally of the tubular member," applicants submit that these independent claims are allowable over Richardson for reasons similar to those given above with respect to claim 1. For at least the reason that claims 3-7, 12-13, 15, 17, 21-22 and 60 depend from one of claims 1, 14 and 59 and contain additional elements, applicants respectfully submit that these claims are allowable over Richardson as well.

Further, with regard to claim 7, which recites "wherein the polymer sheath is disposed over all of the core member," applicants respectfully note that second polymer layer 157 in Figure 20 of Richardson is not shown as extending over the proximal portion of core member 141.

Claims 8, 11, 18 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson in view of Palmer et al., U.S. Patent No. 6,544,231 (hereinafter "Palmer"). Applicants respectfully traverse the rejection on at least two grounds.

First, because these claims depend from one of claims 1 and 14, which applicants submit are patentable, and contain additional elements, applicants submit that these claims are in condition for allowance as well.

Second, Palmer is cited by the Examiner as disclosing "a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding" and the Examiner therefore considers that it would be obvious to make the proposed modification "in order to tightly fuse metal elements together." The problem with this rejection is that the tubular element of Richardson cited as anticipating the tubular member of claim 1 is polymeric. See, for example, Richardson at column 20, lines 8-9. One would not laser-weld the metal coil of Richardson to the polymeric sleeve because one could not. A prima facie case of obviousness has not been made, therefore, at least for the reasons that no motivation to combine the references exists and there is no reasonable chance of success of doing so. For this additional reason, applicants respectfully traverse this rejection.

Claims 9-10 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson in view of Palmer further in view of Cook et al., U.S. Patent No. 5,213,111 (hereinafter "Cook"). Applicants respectfully traverse the rejection.

First, because these claims depend from claims 1 and 14, which applicants submit are allowable, and contain additional elements, applicants submit that these claims are in condition for allowance as well.

Second, Cook is cited as disclosing "a guidewire wherein a coil member 151 is connected to a core member through crimping." However, these claims pertain to the connection of the tubular member to the core; for example, claims 10 recites "wherein the tubular member is connected to the core member through crimping." The proposed modification, therefore, would not result in the claimed invention. Further, the tubular member of Richardson is polymeric, which so far as applicants know, is not a material suitable for crimping. Further, Richardson teaches away from crimping the coil; Richardson teaches a manufacturing process that "can

relieve stresses that can build up during construction of the guidewire 140 and provide for improved handling characteristics." Richardson at column 20, lines 36-39. As crimping the coil would introduce stresses, this process would produce an inferior guidewire while providing no other benefit applicants can discern. For these additional reasons, applicants submit that these claims are allowable over the cited prior art.

Claims 1, 3-7, 12-15, 17, 21-22 and 59-60 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson in view of Hodgson et al., U.S. Patent No. 5,345,945 (hereinafter "Hodgson"). Applicants respectfully traverse the rejection.

With regard to claim 1, the Examiner argues that Richardson discloses everything except a tubular member where the distal end of the tubular member extends distally beyond the distal end of the core member, that Hodgson disclose a guidewire where a coil 100 extends beyond the distal end of a tubular member, and that it would have been obvious to provide a guidewire similar to that of Richardson's with a coil that extends distally beyond the distal end of the tubular member similar to that of Hodgson et al. "since such a modification would serve the same purpose of fluoroscopically tracking and/or imaging the distal end of the guidewire." See the Office Action at pages 11-12.

However, what the Examiner fails to note is that the coil of Richardson is already radiopaque. As discussed in more detail above with regard to the first rejection of claim 1, Richardson teaches that the features of the guidewire of Figure 20 can generally be the same as guidewire 110, where the coils can be radiopaque. See column 20, lines 53-58 and column 18, lines 10-13 of Richardson. As such, adding the coil of Hodgson would be duplicative and thus add complexity and cost without providing any benefit applicants can discern. There is consequently no motivation to modify Richardson in view of Hodgson. For at least this reason, applicants submit that claim 1 is patentable over Richardson in view of Hodgson.

Further, while Hodgson discloses an embodiment where a coil extends distally of a tubular member, it does not follow that adding the coil of Hodgson to Richardson would mean that the coil of Hodgson would likewise extend distally of the tubular member of Richardson. One reason that the distal coil of Hodgson does, and indeed can, extend distally of the tubular member of Hodgson is that the tubular member of Hodgson terminates well proximal of the

distal tip of Hodgson, a configuration that is not present in Richardson. Further, Hodgson teaches that the distal end of the coil terminates proximal of the rounded distal tip of the guidewire. Thus, if one were to modify Richardson in view of Hodgson as suggested (particularly in view of the motivation described on page 11 of the Office Action of "providing a guidewire with a substantially constant outer transverse dimension which translates smoothly in an axial direction within catheter lumens"), one would terminate the distal end of the coil proximally of the rounded distal tip of the catheter. When one does this, the distal end of the coil would not extend distally of the distal end of the tubular member of Richardson. As claim 1 requires that the distal end of the coil extends distally of the distal end of the tubular member, it can be seen that such a modification would not result in the claimed invention.

Applicants thus respectfully submit that a prima facie case of obviousness has not been made for at least the reasons that there is no motivation or suggestion to modify the references as suggested and that the cited references do not teach or suggest all the elements of the invention of claim 1.

As claim 14 recites "wherein the distal end of the coil member extends distally beyond a distal end of the tubular member" and claim 59 recites "a ribbon or wire connected to and extending distally of the tubular member," applicants submit that these independent claims are allowable over Richardson in view of Hodgson for similar reasons to those given above with respect to claim 1. For at least the reason that claims 3-7, 12-13, 15, 17, 21-22 and 60 depend from one of claims 1, 14 and 59 and contain additional elements, applicants respectfully submit that these claims are allowable over Richardson in view of Hodgson as well.

Claims 8, 11, 18 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson in view of Hodgson further in view of Palmer. Applicants respectfully traverse the rejection. For at least the reason that these claims depend from either claims 1 or claim 14, which applicants submit are allowable, and contain additional elements, applicants submit that these claims are in condition for allowance as well.

Claims 9-10 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Richardson in view of Hodgson further in view of Palmer even further in view of Cook.

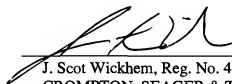
Applicants respectfully traverse the rejection. For at least the reason that these claims depend from either claims 1 or claim 14, which applicants submit are allowable, and contain additional elements, applicants submit that these claims are in condition for allowance as well.

Reexamination, reconsideration, and withdrawal of the outstanding objections and rejections are respectfully requested. It is submitted that all pending claims are now in condition for allowance, and the issuance of a Notice of Allowance in due course is respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By their attorney,

Date: July 30, 2007



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